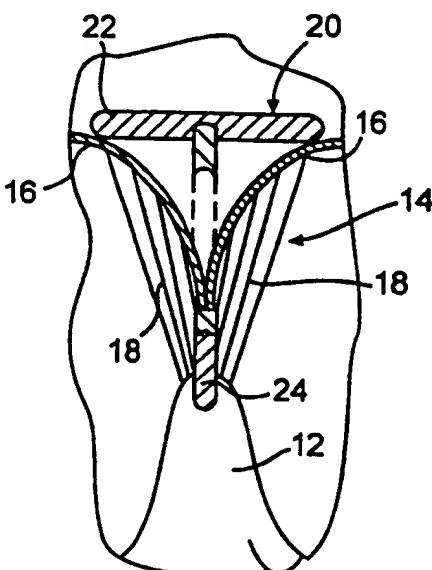


PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/24		A1	(11) International Publication Number: WO 99/30647
			(43) International Publication Date: 24 June 1999 (24.06.99)
(21) International Application Number: PCT/US98/26667		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPo patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 16 December 1998 (16.12.98)		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(30) Priority Data: 08/992,316 17 December 1997 (17.12.97) US			
(71) Applicant (for all designated States except US): MYOCOR, INC. [US/US]; Suite 200W-B, 1380 Energy Lane, St. Paul, MN 55108 (US).			
(72) Inventors; and			
(75) Inventors/Applicants (for US only): MORTIER, Todd, J. [US/US]; 3022 DuPont Avenue South, Minneapolis, MN 55408 (US). SCHWEICH, Cyril, Jr. [US/US]; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US).			
(74) Agents: GARRETT, Arthur, S. et al.; Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., 1300 I Street, N.W., Washington, DC 20005-3315 (US).			
(54) Title: VALVE TO MYOCARDIUM TENSION MEMBERS DEVICE AND METHOD			
(57) Abstract			
<p>A device for heart valve repair including at least one tension member having a first end and second end. A basal anchor is disposed at the first end of the tension member and a secondary anchor at the second end. The method includes the steps of anchoring the basal anchor proximate a heart valve and anchoring the secondary anchor at a location spaced from the valve such that the chamber geometry is altered to reduce heart wall tension and/or stress on the valve leaflets.</p>			
			

VALVE TO MYOCARDIUM TENSION MEMBERS DEVICE AND METHODBackground of the Invention

The present invention pertains generally to the field of heart valve repair. More specifically, the present invention pertains to a device and method for the reduction of myocardial wall tension and the repair of mitral valve insufficiency.

Dilated cardiomyopathy is often accompanied by mitral valve insufficiency. There are several reasons for the presence of mitral valve insufficiency associated with a dilated heart. First, chamber dilation and associated high wall stresses increase the diameter of the mitral valve annulus. Additionally, as the heart dilates, the positioning of the papillary muscles is altered. Papillary muscles and chordae in a dilated heart will have moved both radially away and down from the mitral valve. This rearrangement of the vascular apparatus and enlargement of the annulus prevent the valve from closing properly.

Currently mitral valve insufficiency is treated by either repairing or replacing the valve. Surgical procedures used to repair the valve including ring posterior annuloplasty which consists of sewing a C or D-shaped ring around the posterior leaflet of the mitral valve and drawing in the annulus, reducing its previously enlarged diameter. Another method is to approximate the anterior and posterior mitral leaflets (Alfieri repair) by placing one suture through the center of both leaflets. This gives the valve a figure 8-shaped appearance when the valve is opened. When the mitral valve is replaced, the original leaflets are removed and the chordae are cut. An artificial valve consists of mechanical or tissue leaflets suspended on struts attached to a metal stent, and is sutured into place on the mitral annulus.

It has been argued that valve repair is preferable to valve replacement if the leaflet-chordae-papillary connections can be maintained. Heart wall stress will increase if the chordae are cut during valve replacement. It has been shown that by severing the chordae there can be 30 percent (30%) reduction in chamber function. Mitral valve replacement has high morality in very sick, chronic heart failure patients.

Summary of the Invention

The present invention pertains to a device and method for mitral valve repair. The mitral valve is generally defined as its leaflets or cusps, but in reality, it actually consists of the entire left ventricle chamber. By creating an improved chamber geometry, both chamber and valve function will be improved. The device of the present invention and method for valve repair/replacement can include treatment for chronic heart failure by reducing left ventricular wall tension.

In one embodiment of the present invention, the valve repair device includes an elongate tension member having a first end and second end. The basal anchor is disposed at the first end and the secondary anchor is disposed at the second end.

The basal anchor could include a pad and annuloplasty ring or the like. Alternately an artificial heart valve could serve as the basal anchor.

Tension members can be substantially rigid or substantially flexible. The secondary anchor can include a hook-shaped papillary muscle tissue loop, screw-shaped tissue anchor or transmural anchor pad.

The method of the present invention providing a tension member having a first end and a second end. The tension member has a basal anchor at the first end and a

secondary anchor at the second end. The basal anchor is anchored proximate to the valve such that the tension member is disposed in the chamber. The secondary anchor is anchored to a portion of the heart spaced from the basal anchor such that the tension member is under tension and the geometry of the chamber has been altered by placement of the tension member.

The basal anchor can include an artificial heart valve, annuloplasty ring or the like. The secondary anchor can be anchored to a papillary muscle or transmurally anchored.

More than one tension member can be used. Additionally, a transverse tension member can be placed across the chamber generally perpendicular to the other tension members to further alter the geometry of the heart, reducing wall stress and improving chamber performance.

Brief Description of the Drawings

Figure 1 is a transverse cross section of the left ventricle of a human heart taken from Figure 2;

Figure 2 is a vertical cross section of the left ventricle of a human heart;

Figure 3 is a modified, transverse, cross section of the left ventricle of a human heart taken from Figure 4;

Figure 4 is modified, vertical cross section of a human heart, modified by a device in accordance with the present invention;

Figure 5 is a cross section of an insufficient mitral valve of a left ventricle of a human heart;

Figure 6 is a cross section of a repaired valve and device in accordance with the present invention;

Figure 7 is an embodiment of the device of the present invention;

Figure 8 is an alternate embodiment of a device in accordance with the present invention;

Figure 9 is yet another alternate embodiment of a device in accordance with the present invention;

Figure 10 is yet another alternate embodiment of the device in accordance with the present invention;

Figure 11 is yet another alternate embodiment of a device in accordance with the present invention;

Figure 12 is a view of a basal anchor for the device of the present invention;

Figure 13 is a suture ring serving as a basal anchor for the device of the present invention;

Figure 14 is a replacement valve serving as a anchor for the device of the present invention;

Figure,15 is a top view of an alternate embodiment of a suture ring acting as an anchor for the device of the present invention;

Figure 16 is a side view of the suture ring of Figure 15;

Figure 17 is a view of an alternate embodiment of a suture ring which can act as basal anchor for the device of the present invention;

Figure 18 is a view of yet another alternate embodiment of a suture ring which can act as a basal anchor for the present invention;

Figure 19 is a embodiment of a secondary anchor for the device of the present invention;

Figure 20 is a view of an alternate embodiment of a secondary anchor for the device of the present invention; and

Figure 21 is yet another embodiment of a secondary anchor for the device of the present invention.

Detailed Description of the Invention

Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a transverse cross section of the left ventricle 10 of a failing heart taken from Figure 2. The papillary muscles 12 are shown in cross section. Figure 2 is a vertical cross section of human heart 10. A mitral valve is disposed near the top of left ventricle 10. Mitral valve 14 includes two leaflets or cusps 16. Chordae 18 extend between leaflets 16 and papillary muscles 12.

Figure 3 is a cross section of heart 10 modified from that shown in Figure 1 by placement of valve repair device 20 in accordance with the present invention as shown in Figure 4. Figure 4 is a vertical cross section of left ventricle 10 with geometry modified by device 20. In this embodiment of the invention, device 20 includes a basal anchor 22 such as an annuloplasty or suture ring sewn proximate the annulus of valve 14. Extending from basal anchor 22 are elongate tension members 24. Each have a first end connected to basal anchor 22 and a second end anchored to papillary muscles 12 or the heart wall.

As can be seen in Figures 3 and 4, both the transverse radius and vertical dimension of left ventricle 10 has been reduced in comparison to that of Figures 1 and 2 by drawing papillary muscles 12 toward valve 14 with tension members 24. This change in geometry reduces heart wall stress and consequently increasing chamber function. Valve function is also improved as explained in more detail by reference to Figures 5 and 6.

Figure 5 is a generally vertical cross section of an insufficient mitral valve of a heart suffering from chronic heart failure. In this case as the failing heart has dilated, papillary muscle 12 has been drawn away from

mitral valve 14. The chordae connections between papillary muscles 12 and valve 14 in turn draws leaflets 16 apart such that during the normal cardiac cycle, leaflets 16 may not completely close. Thus, an opening 26 is left between leaflets 16 throughout the cardiac cycle. Opening 26 will allow blood to leak, reducing chamber efficiency.

Figure 6 is a view of the mitral valve 14 of Figure 5 which has been modified by placement of valve repair device 20 as shown. Suture ring 22 is sewn proximate the annulus of valve 14, as known to those skilled in the use of suture rings. The annulus of valve 14 can be decreased in size by drawing the annulus toward the suture ring by the sutures used to connect ring 22 to the valve. Drawing the annulus of valve 14 toward suture ring 22 will help to eliminate opening 26. Tension member 24 is then anchored to papillary muscle 12 such that papillary muscle 12 is drawn toward valve 14. Whether or not the suture ring alone is sufficient to eliminate opening 26, drawing papillary muscle 12 toward valve 14 will provide additional stress relief on leaflet 16 promoting complete closure of valve 14. Drawing papillary muscle 12 toward 14 also reduces heart wall stress and increases chamber efficiency as discussed previously.

Figure 7 is a highly simplified view of left ventricle 10 and valve repair device 20 as shown in Figure 4. It can be noted that tension members 24 extend from basal anchor 22 to an adjacent papillary muscle 12. In contrast, Figure 8 is a similar cross sectional view of left ventricle 10, but a valve repair device 120 is placed such that its tension members 124 extend between a basal anchor 122 and a papillary muscle 12 transversely opposite the point at which tension member 124 is connected to basal anchor 122. This arrangement, as opposed to that shown in Figure 7, can increase the

transverse component of the tension force in tension members 124 relative to the vertical component of that tensile force.

Figure 9 shows yet another embodiment of the valve repair device in accordance with the present invention referred to by numeral 220. In this embodiment, device 220 is disposed in left ventricle 10 in a manner similar to that of device 20 shown in Figure 7 in that tension members 224 of device 220 extend from a basal anchor 222 to an adjacent secondary anchor point. The secondary anchor point is established by transverse extension of a tension member 225 across left ventricle 10. Tension member 225 is anchored transmurally to the heart wall at its opposite ends by pads 227. In turn, tension members 224 are anchored or connected to tension member 225.

Tension member 225 can be used to further alter the geometry of left ventricle 10 in a manner disclosed in U.S. Patent Application Serial No. 08/933,456, entitled "HEART WALL TENSION REDUCTION APPARATUS AND METHOD", which was filed on September 18, 1997 and is incorporated herein by reference.

Figure 10 shows yet another embodiment of a valve repair device in accordance with the present invention referred to by numeral 320. This embodiment includes a basal anchor 322 and tension members 324 and a transverse tension member 325 having anchor pads 327 similar to those of device 220. With respect to device 320, however, tension members 324 are crossed similar to those of device 120 of Figure 8 to increase the horizontal component relative to the vertical component of the tensile force in tension member 324.

Figure 11 is a yet another embodiment 420 of the valve repair device of the present method. Valve repair device 420 includes a basal anchor 422 and tension members 424. Tension members 424 are disposed in an

arrangement similar to tension members 24 of device 20 shown in Figure 7 except that tension members 424 are anchored transmurally by pads 427 rather than into papillary muscles 12. The relatively greater thickness of tension members 424 shown in Figure 11, as compared to tension members 24 shown in Figure 7, merely illustrates that the tension members can be substantially rigid or in the case of tension members 24, substantially flexible. It should be understood, however, that in any of the embodiments shown herein, the tension members could be advantageously formed to be substantially flexible or substantially rigid.

Figure 12 is a top or posterior view of valve 14. In this embodiment, the basal anchor for the valve repair device is shown as discrete pads 28 which can be sewn to the posterior side of valve 14. Tension members 24 are shown extending from respective pads 28 into the left ventricle.

Figure 13 is the same view of valve 14 as Figure 12. In Figure 13, however, the basal anchor 22 is shown as a crescent-shaped suture ring. Tension members 24 extends from basal anchor 22 through valve 14 into the left ventricle.

Figure 14 is a side view of an artificial heart valve 30. If it is necessary to replace the valve rather than merely repair it, artificial valve 30 can be used as a basal anchor for tension members 24.

Figure 15 is a top view of an alternate embodiment of a suture ring basal anchor 32. Ring 32 has a crescent shape and a pylon 34 extending through the mitral valve. Figure 16 is a side view of suture ring 32 showing tension members 24 attached to pylon 34.

Tension members 24 preferably extend through the tissue of valve 14 rather than through the valve opening. It can be appreciated, however, that tension members 24

could be disposed through the valve opening. In the case of the embodiment of Figures 15 and 16, however, pylon 34 would be disposed through the valve opening. Tension members 24 associated with pylon 34 would be disposed on the opposite side of valve 14 from suture ring 32. Pylon 34 would preferably be disposed through the valve opening rather than the tissue forming valve 14.

Figures 17 and 18 are yet additional alternate embodiments of suture rings which can be used as basal anchors in accordance with the present invention. The shape of the rings is selected such that as they are sewn into place on valve 14, the sutures can be used to draw tissue toward the inside of the ring, thus reducing the transverse and/or vertical cross sectional area of the associated heart chamber. This will advantageously reduce heart wall stress which is of particular benefit if the patient has a failing heart.

It can be appreciated that tension members 24 can be fixably or releasably attached to the basal anchor. Preferably, the tension members are fixably attached to the basal anchor during the valve repair procedure.

Figures 19-21 show various configurations of anchoring devices shown at the second end of tension member 24. It can be appreciated that these anchoring devices could be used with each of the tension members described above. In Figure 19, the second end of tension member 24 includes a secondary anchor 40 formed as screw which is shown augured into papillary muscle 12. Figure 20 shows a secondary anchor 42 including a loop sewn through papillary muscle 12. Figure 21 shows a tension member 24 extending transmurally to an exterior pad 44 to which it is connected. Tension member 24 could be sewn to pad 44 or otherwise mechanically connected thereto.

It can be appreciated that various biocompatible materials can be advantageously used to form the various

components of the device of the present invention. It is anticipated that the present device will usually be chronically implanted. Thus, when selecting materials to form each of the components consideration should be given to the consequences of long term exposure of the device to tissue and tissue to the device.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A valve repair device, comprising:
an elongate tension member having a first end and
second end;
a basal anchor disposed at the first end; and
a secondary anchor disposed at a second end.
2. A valve repair device in accordance with claim 1, wherein the basal anchor includes a pad.
3. A valve repair device in accordance with claim 1, wherein the basal anchor includes annuloplasty ring.
4. A valve repair device in accordance with claim 1, wherein the basal anchor includes an artificial heart valve.
5. A valve repair device in accordance with claim 1, wherein the basal anchor includes a suture ring having a varying radius of curvature.
6. A valve repair device in accordance with claim 1, wherein the tension member is substantially rigid.
7. A valve repair device in accordance with claim 1, wherein the tension member is substantially flexible.
8. A valve replacement device in accordance with claim 1, wherein the secondary anchor includes a hook-shaped papillary muscle tissue loop.
9. A valve repair device in accordance with claim 1, wherein the secondary anchor includes a screw-shaped tissue anchor.

10. A valve repair device in accordance with claim 1, wherein the secondary anchor includes a transmural anchor pad.

11. A method of repairing a heart valve having leaflets and chordae disposed in a heart chamber, comprising the steps of:

providing a tension member having a first end and a second end, the tension member having a basal anchor at the first end and a secondary anchor at the second end;

anchoring the basal anchor proximate the valve such that the tension member is disposed in the chamber; and

anchoring the secondary anchor to a portion of the heart spaced from the basal anchor such that the tension member is under tension and the geometry of the chamber has been altered by placement of the tension member.

12. The method in accordance with claim 11, wherein the basal anchor includes an artificial heart valve.

13. The method in accordance with claim 11, wherein the basal anchor includes an annuloplasty ring.

14. The method in accordance with claim 11, wherein the secondary anchor is anchored to a papillary muscle.

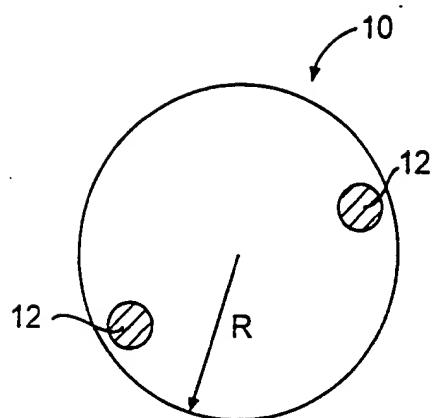
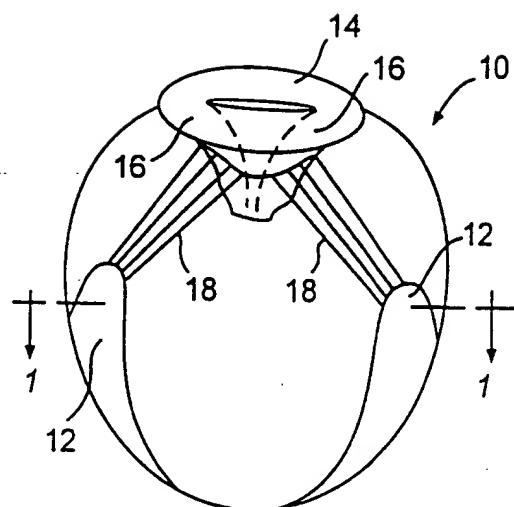
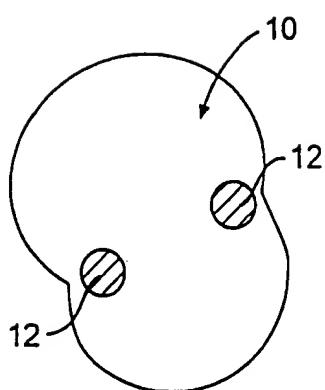
15. The method in accordance with claim 11, wherein the secondary anchor is transmurally anchored.

16. The method in accordance with claim 11, wherein at least two tension members are provided.

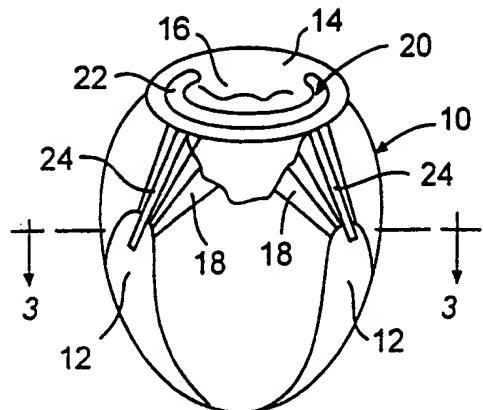
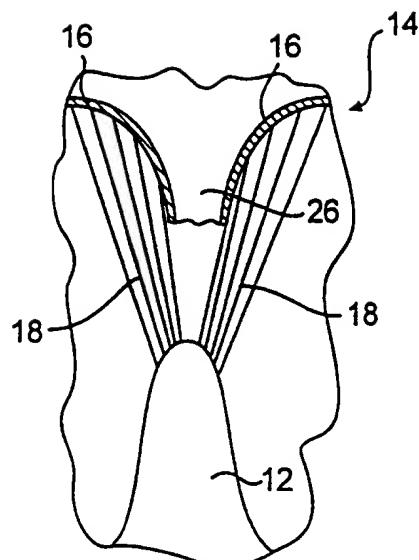
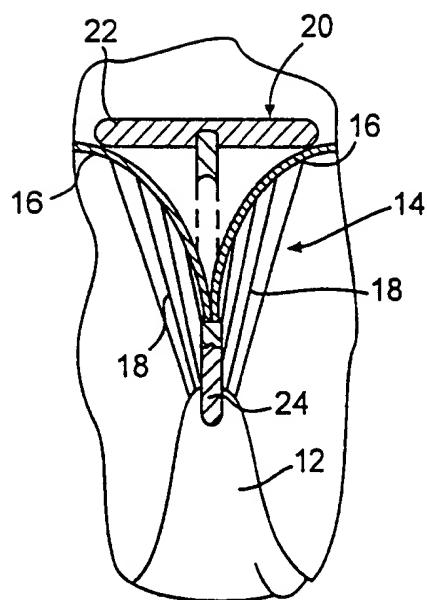
17. The method in accordance with claim 11, further comprising the step of placing a transverse tension member across the chamber, generally perpendicular to the

tension member, to further alter the geometry of the chamber.

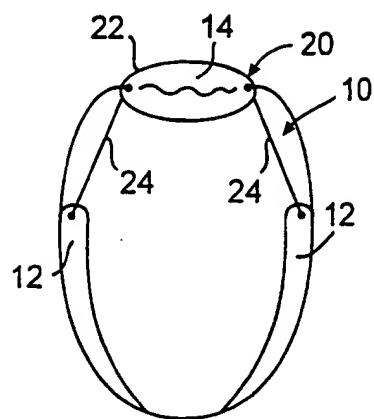
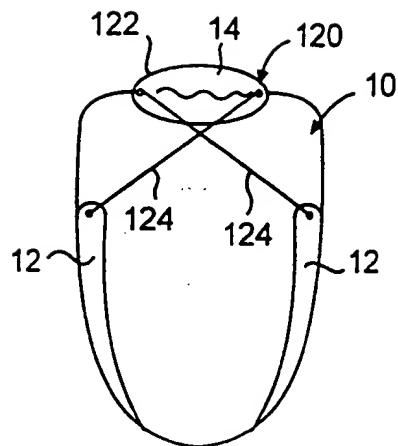
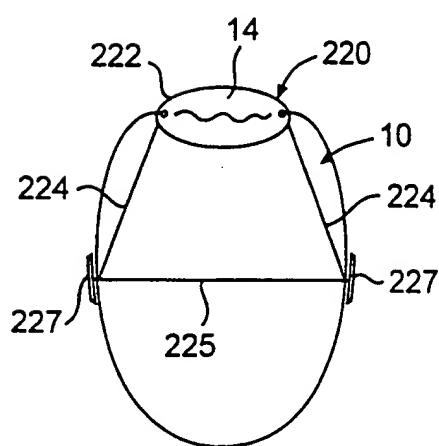
1/7

**FIG. 1****FIG. 2****FIG. 3**

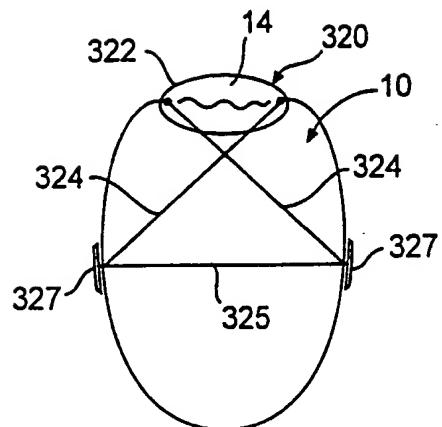
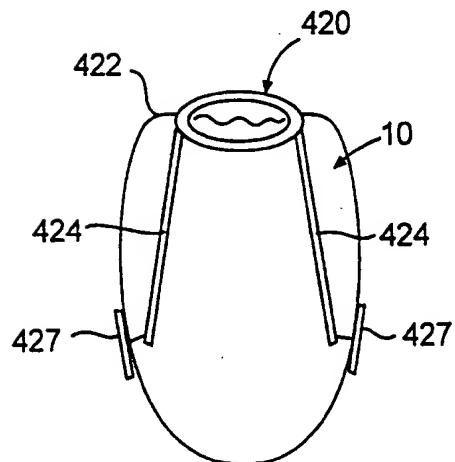
2/7

**FIG. 4****FIG. 5****FIG. 6**

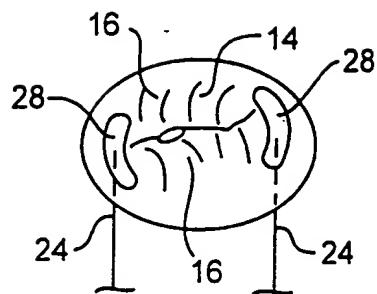
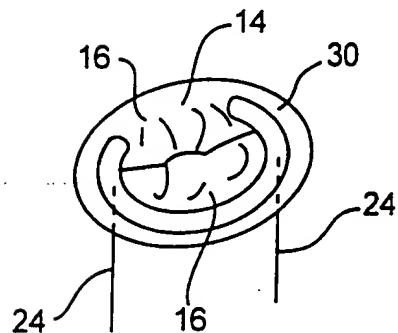
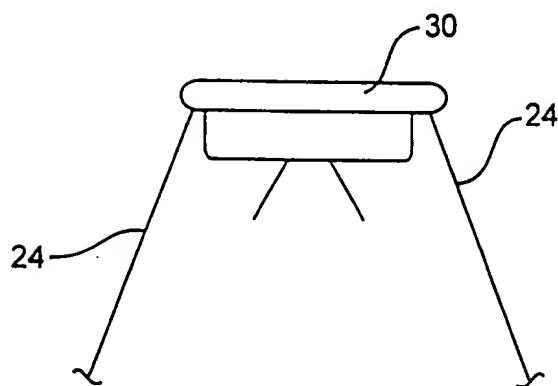
3/7

**FIG. 7****FIG. 8****FIG. 9**

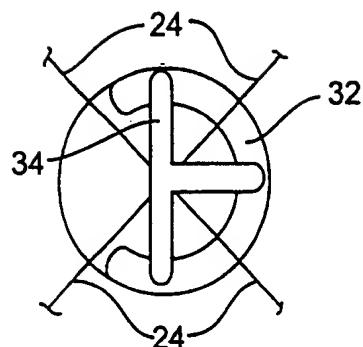
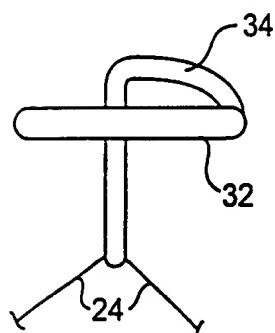
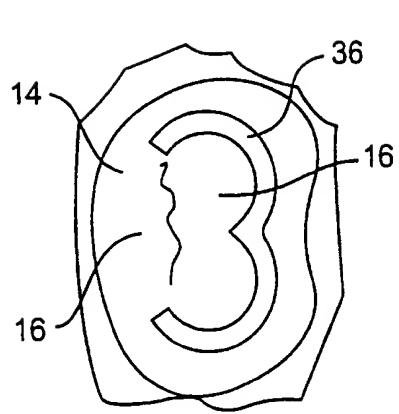
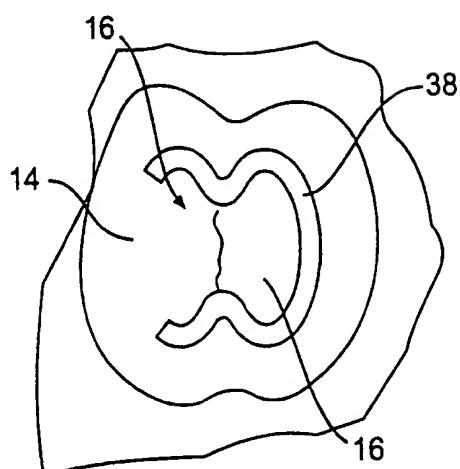
4/7

**FIG. 10****FIG. 11**

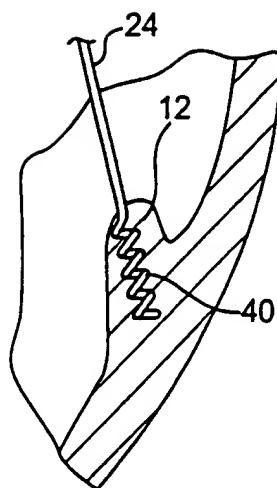
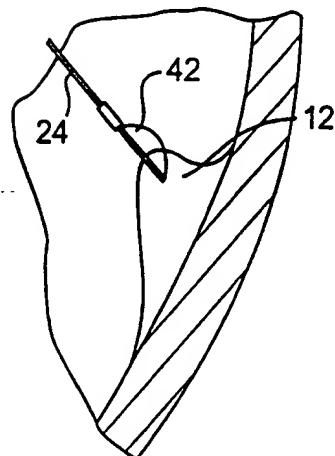
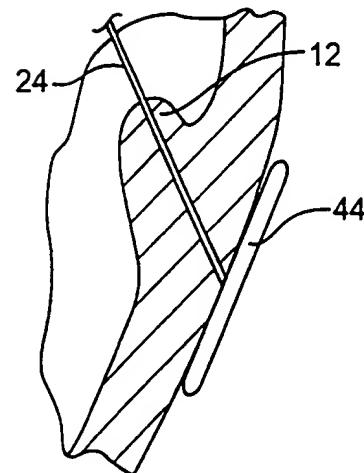
5/7

**FIG. 12****FIG. 13****FIG. 14**

6/7

**FIG. 15****FIG. 16****FIG. 17****FIG. 18**

7/7

FIG. 19**FIG. 20****FIG. 21**

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 98/26667

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
--

C. DOCUMENTS CONSIDERED TO BE RELEVANT
--

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 06447 A (W.L. GORE & ASSOCIATES, INC.) 9 March 1995 see page 16, line 26 - page 17, line 2; figures 16,17	1
A	WO 96 04852 A (NORTHRUP) 22 February 1996	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *S* document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
---	--

19 April 1999

26/04/1999

Name and mailing address of the ISA	Authorized officer
-------------------------------------	--------------------

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel: (+31-70) 340-2040, Tx: 31 651 epo NL
Fax: (+31-70) 340-3015

Smith, C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/26667

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 11-17
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

THIS PAGE BLANK (USPTO)